U. S. ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

Date: 12/02/03

Subject: **FENHEXAMID** Residue Chemistry Summary Document for:

PP# 2E6463 Kiwifruit
PP# 2E6496 Fruiting Vegetables (Group 8) and Cucumber
PP# 3E6532 Leafy Greens (Subgroup 4A), except spinach; Cilantro
PP# 3E6541 Stone Fruit (Group 12) - (add postharvest use and raise existing tolerances)

DP Barcode: **D285209, D285214, D287732, D287860**
PC Code: 090209
40 CFR: 180.553
MRID#s: 45682001, 45736601, 45736602, 45736603, 45736604, 45736605, 45736606, 45795601, 45817101, 45821101, 45821102, 45821103.

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1.0 BACKGROUND

The Interregional Research Project No. 4, on behalf of the Agricultural Experiment Stations of various States, has submitted the subject petitions proposing the establishment (raising, for stone fruit) of permanent tolerances for residues of the fungicide, fenhexamid, in/on:

Kiwifruit	15.0 ppm
Vegetable, fruiting, group 8	2.0 ppm
Cucumber	2.0 ppm
Leafy greens, subgroup 4A, except spinach	30.0 ppm
Fruit, stone, group 12	10.0 ppm

The Data Evaluation Records (DERs) accompanying this review were prepared by the California Department of Pesticide Regulation (CDPR) and were peer-reviewed by RAB2/HED in a joint review project.

2.0 CHEMICAL IDENTITY

TABLE 2.1. Test Compound Nomenclature	
Compound	Chemical Structure
Common name	Fenhexamid
Company experimental name	KBR 2738
IUPAC name	2,3-dichloro-4-(1-methylcyclohexyl-carbonylamine)-phenol
CAS name	N-(2,3-dichloro-4-hydroxyphenyl)-1-methyl-cyclohexanecarboxamide
CAS #	126833-17-8
End-use product/EP	ELEVATE 50 WDG Fungicide, EPA Reg. No. 66330-35

TABLE 2.2. Physicochemical Properties of the Technical Grade Test Compound		
Parameter	Value	Reference
Melting point/range	153 °C	Fenhexamid: Pesticide Fact Sheet (May 20, 1999) Fenhexamid (KBR 2738)- a Botryticide from a New Chemical Class, Pflanzenschutz-Nachrichten Bayer 52/1999, 2
pH	8.3 in 1% solution of water	
Density	1.34 g/ml @ 20 °C	
Water solubility (20°C)	20 mg/l	
Solvent solubility (mg/L at 20°C)	dichloromethane: 31000, 2-propanol: 91000, n-hexane: < 100, Toluene: 5700	
Vapor pressure at 25°C	$7x10^{-9}$ Torr	
Dissociation constant (pK_a)	7.3	
Actinal/water partition coefficient $Log(K_{OW})$	3.51 (pH 7, 20 °C)	
UV/visible absorption spectrum	245 and 290 nm	

3.0 PROPOSED LABEL USE PATTERNS

TABLE 3.1. Proposed Directions for Use on the Subject Crops

Preharvest Use

Crop	Applications							
	EP [1]	Type	Max. Rate lb ai/ A	RTI [2] days	Number. and Timing	Seasonal Rate lb ai/A	PHI, days	Tank Mix Adjuvants
Fruiting Vegetables, group 8	50 WDG	foliar-directed	0.75	7-10	≤4, as needed. For transplant production & greenhouse use only. **Do not apply in the field.**	up to 3	0	Optional
Cucumber	50 WDG	Same Use Pattern as Fruiting Vegetables.						
Leafy Greens, Subgroup 4a	50 WDG	foliar-directed	0.75	7	1-2, as needed. For transplant production & greenhouse use only. **Do not apply in the field.**	up to 1.5	3	Optional
Cilantro, leaves	50 WDG	Same Use Pattern as Leafy Greens.						
Stone Fruit, Group 12	50 WDG	foliar-directed	0.75	≤4. At early bloom, late bloom, 2 weeks after petal fall, and harvest		up to 3.0	0	Optional

Postharvest Use

Crop	Application			
	EP	Type	No.	Procedure for Applying
Kiwifruit	50 WDG	packing line spray **or** fruit dip	1	Apply EITHER as a packing line spray of 0.75 lb ai/8-20 gals water/200,000 lbs of fruit OR dip fruit in a solution of 0.75 lb ai/100 gals of water for 20-30 seconds.
Stone Fruit, Group 12, except Cherry	50 WDG	packing line spray **or** fruit dip	1	Apply 0.75 lb ai per 100 gals of water or wax/oil emulsion per 200,000 lbs of fruit. Apply EITHER as a packing line spray OR dip fruit in the solution for 30 sec.
Cherry (Sweet and Tart)	50 WDG	packing line spray **or** fruit dip	1	Apply 0.75 lb ai/100 gals of water or wax/oil emulsion per 25,000 lbs of fruit. Apply EITHER as a packing line spray OR dip fruit in the solution for 30 sec.

1 End Use Product
2 Retreatment Interval

3 Not Specified

4.0 DER EXECUTIVE SUMMARIES

4.1 CROP RESIDUES (from Pre- and/or PostHarvest Application) - Kiwifruit, Plum, Peach, Cherry, Lettuce, Cucumber, Pepper, and Tomato
(DER of MRIDs 45682001, 45821101, 45821102, 45821103, 45795601, 45817101, 45736603, 45736604, 45736605, 45736606, 45736601, and 45736602)

Supervised residue trials (3) were conducted in CA (2) and OR (1) with kiwifruit (PP# 2E6463) treated ONLY by a single postharvest application of TM-402 50% WDG (equivalent to Elevate 50 WDG) as a packing line spray (CA) or as a 30 second dip treatment (CA, OR). The packing line spray was applied at a rate of approximately 0.75 lb ai/200,000 lb fruit in 8 to 20 gallons of water (low volume). The fruit dip was a solution of approximately 0.75 lb ai/100 gal of water. Samples were frozen stored up to 151 days prior to analysis by HPLC/UV for fenhexamid residues. Residues of fenhexamid ranged from 2.5 to 7.1 ppm in samples treated with the packing line spray, and from 6.5 to 12.5 ppm in samples that were dipped.

Supervised residue trials (2) on plum (fresh prune) (PP#3E6541) were conducted in CA to support combined preharvest and postharvest uses. A preharvest use is currently registered. Each of the two field trial sites consisted of one untreated control plot and one treated plot. Each treated plot received two foliar-directed applications of TM-402 50% WDG, 50% ai, at a rate of 0.75 lb ai/A, for a total of 1.50 lb ai/A. The applications were made 7 days apart. Untreated and treated mature plum fruit were collected on the day of the second field application and subsamples of each were subjected to a postharvest treatment using either a packing line spray or a 30 second dip. The packing line spray application was conducted at a rate of 0.75 lb ai/200,000 lb fruit in either a low volume (7 gallons) or high volume (100 gallons) of water. The dip application was conducted at a rate of 0.75 lb ai/100 gal. The adjuvant Decco Lustr 251 was included in the tank mixes. All samples were frozen stored for up to 231 days and then analyzed by HPLC/UV for fenhexamid residues. The maximum residue reported: in plums treated only by preharvest application was <0.10 ppm; in field-untreated plums treated only by postharvest packing line spray was 0.42 ppm; in field-untreated plums treated only by postharvest dip was 0.71 ppm; in field-treated plums also receiving a postharvest packing line spray was 0.40 ppm; and in field-treated plums also receiving a postharvest dip application was 0.66 ppm. A residue decline study was not conducted with plum.

Supervised residue trials (3) were conducted with peach (PP#3E6541) in NJ, NC and CA to support combined preharvest and postharvest uses. A preharvest use is currently registered. In each trial, peach trees in the treated plot received two applications of TM-402 50% WDG, 50% a.i., at 0.75 lb a.i./A. Applications were made one week apart. Untreated and treated mature peach fruit were collected on the day of the second field application and subsamples of each were subjected to a post-harvest treatment using either a packing line spray or a 30 second dip. The packing line spray application was applied at a rate of approximately 0.75 lb ai/200,000 lb fruit in either a low volume (25 gallons) or high volume (100 gallons) of water. The dip application rate was approximately 0.75 lb ai/100 gal. The adjuvant Decco Lustr 251 was included in the tank mixes. All samples were frozen stored for up to 218 days and then analyzed by HPLC/UV for fenhexamid residues. The maximum residue reported: in peaches treated only by preharvest application was 2.1 ppm; in field-untreated peaches treated only by postharvest packing line spray was 4.2 ppm; in field-untreated peaches treated only by postharvest dip was 6.6 ppm; in field-treated peaches also receiving a postharvest packing line spray was 4.4 ppm; and in field-treated peaches also receiving a postharvest dip application was 7.2 ppm. A residue decline study was not conducted with peaches.

Supervised residue trials (4) on sweet cherry (PP#3E6541) were conducted in WA (2), MI and CA to support combined preharvest and postharvest uses. A preharvest use is currently registered. In each trial, cherry trees in the treated plot

received two foliar-directed sprays at a 7-day retreatment interval of TM-402 50% WDG, 50% a.i., at 0.75lb a.i./A, which corresponds to the currently registered Elevate 50 WDG label maximum application rate on stone fruit. Untreated and treated mature cherry fruit were collected on the day of the second field application and subsamples of each were subjected to a single postharvest packing line spray application at a rate of 0.75 lb ai/25,000 lb fruit in 100 gallons (high volume) of water. The adjuvant Decco Lustr 251 was included in the tank mixes. All samples were frozen stored up to 196 days (296 days for 2 samples) and then analyzed by HPLC/UV for fenhexamid residues. The maximum residue reported: in cherries treated only by preharvest application was 1.2 ppm; in field-untreated cherries treated only by postharvest application was 2.9 ppm; and in field-treated cherries also receiving a postharvest application was 3.8 ppm. No data were submitted for tart cherry samples treated postharvest or for sweet cherry samples treated postharvest by fruit dip. A residue decline study was not conducted with cherry.

Supervised residue trials (4 head, 4 leaf) were conducted in Germany and Italy with greenhouse-grown lettuce (PP# 3E6532). In each trial, lettuce plants were treated twice with Teldor 50 WG (equivalent to Elevate 50 WDG), 50% ai, at 0.67 lb ai/A (0.75 kg ai/ha) for a seasonal total of 1.34 lb ai/A. Samples were harvested at PHIs of 0-7 (or 10) days to observe residue decline. Samples were frozen stored up to 297 days prior to analysis by HPLC/UV for fenhexamid residues. Residues in head lettuce ranged from 1.3-23 ppm, with the maximum residue at a 3-day PHI being 21 ppm. Residues in leaf lettuce ranged from 2.3-23 ppm, with the maximum residue at a 3-day PHI being 23 ppm.

Supervised residue trials (8) were conducted in Benelux, Italy (2), Greece, Spain (2), Belgium, and Germany with greenhouse-grown cucumber plants (PP#2E6496). In each trial, cucumber plants were treated three times with KBR 2738 (50WG), 50% ai, (equivalent to Elevate 50 WDG) at 0.67 lb ai/A (0.75 kg ai/ha), for a seasonal total of 2.0 lb ai/A. Samples were harvested at PHIs of 0-3 (or 7) days to observe residue decline. Samples were frozen stored up to 274 days prior to analysis by HPLC/UV for fenhexamid residues. Residues ranged from <0.05 ppm (7-day PHI) to 1.0 ppm (0-day PHI).

Supervised residue trials (9) were conducted in the Netherlands (2), France (2), Italy (3), Spain, and Portugal with greenhouse-grown bell pepper plants (PP#2E6496). Pepper plants were treated three times with KBR 2738 (50WG), 50% ai, at 0.67 lb ai/A (0.75 kg ai/ha), for a seasonal total of 2.0 lb ai/A. Samples were harvested at PHIs of 0-3 (or 7) days to observe residue decline. Samples were frozen stored up to 157 days prior to analysis by HPLC/UV for fenhexamid residues. Residues ranged from 0.20 ppm (7-day PHI) to 1.1 ppm (0-day PHI).

Supervised residue trials (8) were conducted in France (2), Italy (3), Germany, Belgium, and Greece with greenhouse-grown tomato plants (PP#2E6496). In each trial, tomato plants were treated three times with KBR 2738 (50WG), 50% ai, at 0.67 lb ai/A (0.75 kg ai/ha), for a seasonal total of 2.0 lb ai/A. Samples were harvested at PHIs of 0-3 (or 7) days to observe residue decline. Samples were frozen stored up to 164 days prior to analysis by HPLC/UV for fenhexamid residues. Residues ranged from 0.23 ppm (7-day PHI) to 1.2 ppm (1-day PHI). The maximum residue at 0-day PHI was 0.85 ppm.

Bayer AG "Method for determination of KBR 2738 (TM-402) residues in plant material by HPLC", J. Bachmann and F. Nublein, dated 6-16-95, was used to determine residues of fenhexamid per se. Adequate concurrent recoveries were obtained for kiwi (86-120% for 0.1 ppm spikes), plum (82-120% for 0.1-10 ppm), sweet cherry (96-110% for 1.0 ppm), lettuce (60-105% for 0.05-10 ppm), peach (90-110% for 1.0-10 ppm), cucumber (63-82% for 0.05-5.0 ppm), pepper (73-103% for 0.05-5.0 ppm) and tomato (79-99% for 0.05-0.5 ppm).

The numbers of trials for all the above crops are adequate to represent postharvest or greenhouse uses. Frozen storage stability studies on kiwi, peaches, cherries, and tomatoes are reviewed in a companion DER (of MRIDs 45682001, 45821102, 45821103, 45736601, and 45736602). The storage stability data support all of the above field trial data.

4.2 STORAGE STABILITY - Kiwifruit, Peach, Cherry, and Tomato (DER of MRIDs 45682001, 45821102, 45821103, 45736601, and 45736602)

This storage stability study with kiwifruit (PP#2E6463) was conducted in support of the fenhexamid/kiwifruit residue study (reviewed in the DER of MRID 45682001) in which samples were frozen stored 151 days prior to analysis. Chopped kiwifruit samples from untreated controls were fortified with 5.0 ppm fenhexamid and stored in a freezer at < -20 °C for 145 days. Stored samples were then analyzed by HPLC/UV for residues of fenhexamid. Recoveries ranged from 90 to 92 %.

This storage stability study with peaches (PP# 3E6541) was conducted in support of the fenhexamid residue study (reviewed in the DER of MRIDs 45821101 & 45821102) in which samples of peaches and plums were frozen stored 218 and 231 days, respectively, prior to analysis. Chopped peach samples from untreated controls were fortified with 5.0 ppm fenhexamid and stored in a freezer at -21±7 °C for 221-223 days. Stored samples were then analyzed by HPLC/UV for residues of fenhexamid. Recoveries ranged from 76 to 84%.

This storage stability study with sweet cherries (also PP#3E6541) was conducted in support of the fenhexamid residue study (reviewed in the DER of MRID 45821103) in which most cherry samples were frozen stored ≤196 days (two samples were stored 296 days) prior to analysis. Chopped cherry samples from untreated controls were fortified with 5.0 ppm fenhexamid and stored in a freezer at –37.2 to –8.5 °C for 216 days. Stored samples were then analyzed by HPLC/UV for residues of fenhexamid. Recoveries ranged from 76 to 82%.

This storage stability study with tomatoes (PP#2E6496) was conducted in support of the fenhexamid /tomato, pepper, lettuce and cucumber crop residue studies (reviewed in the DER of MRIDs 45736601/45736602, 45736605/45736606, 45795601/45817101, and 45736603/ 45736604) in which samples were frozen stored up to 164, 157, 297, and 274 days, respectively, prior to analysis. Chopped tomato samples from untreated controls were fortified with 0.5 ppm fenhexamid and frozen stored at < -18 °C for 365 days. Stored samples were then analyzed by HPLC/UV for residues of fenhexamid. Recoveries were reported as "comparable to method suitability recoveries".

Bayer AG "Method for determination of KBR 2738 (TM-402) residues in plant material by HPLC", J. Bachmann and F. Nublein, dated 6-16-95, was used to determine residues of fenhexamid per se. Adequate concurrent recoveries were obtained for kiwi (86-120% for 0.1 ppm spikes), plum (82-120% for 0.1-10 ppm), sweet cherry (96-110% for 1.0 ppm), lettuce (60-105% for 0.05-10 ppm), peach (90-110% for 1.0-10 ppm), cucumber (63-82% for 0.05-5.0 ppm), pepper (73-103% for 0.05-5.0 ppm) and tomato (79-99% for 0.05-0.5 ppm).

The storage stability data for kiwifruit, peach, cherry, and tomato indicate that fenhexamid is stable on these crops under the conditions of the study.

5.0 CONCLUSIONS

OPPTS 830 Series GLNs: Product Properties

5.1 The product chemistry data for fenhexamid technical has previously been reviewed (D250226, 12/28/98, H. Podall, RD). No additional data are required in support of these subject petitions.

OPPTS GLN 860.1200: Proposed Uses

5.2 The proposed use directions for fenhexamid on the subject crops are adequately described (abridged summary in Section 3.0 of this review).

OPPTS GLN 860.1300: Nature of the Residue - Plants

5.3 No new plant metabolism studies were submitted. Acceptable fenhexamid metabolism studies on grapes, tomatoes, and apples have previously been submitted and reviewed by HED (D244844 & D249061, 3/25/99, G. Herndon). The results of those metabolism studies indicate that most of the terminal residue is unmetabolized parent. Fenhexamid residues are non-systemic and primarily surface residues; there is very little translocation of radioactive residues. HED's Metabolism Assessment Review Committee (MARC) has concluded (D253792, 3/11/99, G. Herndon) that only residues of parent fenhexamid *per se* need to be included in the tolerance expression and used for dietary risk assessment for crops and drinking water. Metabolism studies labeled in a different position are not required; however, *additional ^{14}C-fenhexamid metabolism studies (on dissimilar crops) may be required to support future requests for tolerances and registrations.* For the purposes of the petitions being reviewed by this memo, the qualitative nature of fenhexamid residues in plants is adequately understood; parent fenhexamid *per se* comprises the residue to be regulated.

OPPTS GLN 860.1300: Nature of the Residue - Animals

5.4 No new ruminant metabolism study was submitted. A fenhexamid goat metabolism study has previously been submitted and evaluated (D254137, 2/2/00, M. Nelson). The qualitative nature of fenhexamid residues in ruminants is adequately understood. The metabolism of fenhexamid in the goat is similar to that in the rat. In both these species fenhexamid undergoes hydroxylation of the cyclohexyl ring to produce 4-hydroxy-fenhexamid and conjugation of the aromatic hydroxyl group to produce the glucuronic acid conjugates of fenhexamid and 4-hydroxy-fenhexamid. At this time none of the subject uses of fenhexamid are on crops with significant livestock feed items. *The residue of concern in ruminants will be determined in the future by HED's MARC, if/when a use is proposed that may result in secondary residues in products of animal origin.*

5.5 A poultry metabolism study was not submitted, and is not currently required, as there are no significant poultry feed items associated with the proposed or established uses of fenhexamid.

OPPTS GLN 860.1340: Analytical Methods - Plants

5.6 Bayer AG method, "Method for determination of KBR 2738 (TM-402; fenhexamid) residues in plant material by HPLC", J. Bachmann and F. Nublein, dated 6-16-95, was used as the data collection method for the determination of fenhexamid in raw agricultural commodities. Residues of fenhexamid were extracted with acetone and filtered. After evaporation of acetone the aqueous residues were cleaned up on a ChemElute column and eluted with cyclohexane /ethyl acetate (85/15). The samples were then evaporated to dryness and taken up in 100% methanol.. The analyte was analyzed by HPLC equipped with an UV detector at 289 nm wavelength. Validated Limits of Quantification (LOQ) of 0.1 ppm for kiwifruit and stone fruit, and 0.05 ppm for lettuce, cucumber, pepper and tomato were reported. The method appears adequate for data collection purposes.

5.7 Bayer AG Method 00362 (HPLC - ECD) is the tolerances enforcement method for fenhexamid residues. It has previously undergone a successful independent laboratory validation (ILV) using grapes as the test matrix. The method has also undergone successful validation by the Analytical Chemistry Branch (ACB)/BEAD. A copy of Bayer AG Method 00362 has been sent to FDA for publication in the Pesticide Analytical Manual (PAM), Volume II, as a Roman numeral method. In the interim, it is available through ACB/BEAD (7503W).

OPPTS GLN 860.1340: Analytical Methods - Animals

5.8 Not presently applicable. To date, residues of fenhexamid in animal commodities have been classified as 40 CFR 180.6(a)(3) - no reasonable expectation of finite residues. There are no livestock feed items of regulatory interest associated with the subject petitions.

OPPTS GLN 860.1360: Multiresidue Methods

5.9 Fenhexamid has previously been subjected to testing via the FDA multiresidue methods protocols. Fenhexamid was adequately recovered (>80%) from non-oily matrices using Protocol B, but recovery from an oily matrix was only ca 15% (PP#7F4890).

OPPTS GLN 860.1380: Storage Stability Data

5.10 Freezer storage stability data were submitted for kiwifruit (145 days), peach (223 days), cherry (216 days) and tomato (365 days) which demonstrated the relative stability of fenhexamid residues in fortified samples for a duration of time equivalent to the storage intervals of the treated samples. These data adequately support the crops in the subject petitions.

5.11 If the petitioner opts to conduct a plum processing study (see §5.25), supporting freezer storage stability data will need to be generated for the duration of the storage interval of processed samples prior to residue analysis, if the duration exceeds 30 days.

OPPTS GLN 860.1480: Meat/Milk/Poultry/Eggs

5.12 No livestock feed items of regulatory interest are associated with the subject petitions. Thus, this topic is not germane to this review.

OPPTS GLN 860.1500: Supervised Crop Residue Trials

Kiwifruit

5.13 Three supervised residue trials with **kiwifruit** were conducted by the proposed use pattern (no preharvest application; one postharvest application by spray or dip per Table 3.1). Samples were frozen stored (≤151 days) prior to analysis by HPLC/UV for fenhexamid residues. Residues ranged from 2.5 to7.1 ppm in samples treated with the packing line spray, and from 6.5 to **12.5 ppm** in samples that were dipped. The data support the proposed tolerance of **15.0 ppm** for kiwifruit.

Stone Fruit - **Summary from PP#7F4890**, D254137, of Preharvest Data.

5.14 Field trial data were submitted for cherries (sweet and tart)(6 trials), peaches (10 trials), and plums (6 trials), which are the three representative commodities of the stone fruits crop group. Samples (U.S. field trials) were harvested 0-days following the last of four sequential foliar applications of the 50% WDG formulation at 0.73-0.78 lb ai/A/ application (3.0 lbs ai/A/season; 1x the proposed maximum seasonal application rate). Residues of fenhexamid in/on treated samples ranged 0.84-**1.8 ppm for sweet cherry**, 1.05-**4.9 ppm for tart cherry**, 0.33-**2.1 ppm for peach**, and <0.05-**0.37 ppm for plum**.

Stone Fruit - Plum (representative crop of group 12)

5.15 Supervised residue trials (2) on **plum** (fresh prune) were conducted to support a postharvest use. A preharvest use is currently registered (see **§5.14** for data summary). Each of the two field trial sites consisted of one untreated control plot and one treated plot. Each treated plot received two foliar-directed applications of TM-402 50 WDG at a rate of 0.75 lb ai/A, for a total of 1.50 lbs ai/A. The applications were made 7 days apart. Untreated and treated mature plum fruit were collected on the day of the second field application and subsamples of each were subjected to a postharvest treatment using either a packing line spray or a 30 second dip per Table 3.1. All samples were frozen stored for up to 231 days and then analyzed by HPLC/UV for fenhexamid residues. The maximum residue reported: in plums treated only by preharvest application was <0.10 ppm **(0.37 ppm** per **§5.14**); in field-untreated plums treated only by postharvest packing line spray was 0.42 ppm ; in field-untreated plums treated only by postharvest dip was **0.71 ppm**; in field-treated plums also receiving a postharvest packing line spray was 0.40 ppm; and in field-treated plums also receiving a postharvest dip application was 0.66 ppm. It is noted that in these 2 trials only the two late season preharvest applications were made (and the two earlier season ones also permitted by the proposed label were omitted). However, in the 6 field trials previously submitted (see §5.14), all four preharvest applications were made, per the proposed label. See **§5.18** for discussion of appropriate tolerance level.

Stone Fruit - Peach (representative crop of group 12)

5.16 Supervised residue trials (3) were conducted with **peach** to support a postharvest use. A preharvest use is currently registered (see **§5.14** for data summary). In each trial, peach trees in the treated plot received two applications of TM-402 50% WDG, 50% a.i., at 0.75 lb a.i./A. Applications were made one week apart. Untreated and treated mature peach fruit were collected on the day of the second field application and subsamples of each were subjected to a post-harvest treatment using either a packing line spray or a 30 second dip per Table 3.1. All samples were frozen stored for up to 218 days and then analyzed by HPLC/UV for fenhexamid residues. The maximum residue reported: in peaches treated only by preharvest application was **2.1 ppm** (also 2.1 ppm per §5.14); in field-untreated peaches treated only by postharvest packing line spray was 4.2 ppm; in field-untreated peaches treated only by postharvest dip was 6.6 ppm; in field-treated peaches also receiving a postharvest packing line spray was 4.4 ppm; and in field-treated peaches also receiving a postharvest dip application was **7.2 ppm**. It is noted that in these 3 trials only the two late season preharvest applications were made (and the two earlier season ones also permitted by the proposed label were omitted). However, in the 10 field trials previously submitted (see §5.14), all four preharvest applications were made, per the proposed label. See **§5.18** for discussion of appropriate tolerance level.

Stone Fruit - Cherry (representative crop of group 12)

5.17 Supervised residue trials (4) on **sweet cherry** were conducted to support a postharvest use. A preharvest use is currently registered (see **§5.14** for data summary). In each trial, cherry trees in the treated plot received two foliar-directed sprays at a 7-day retreatment interval of TM-402 50 WDG at 0.75lb a.i./A. Untreated and treated mature cherry fruit were collected on the day of the second field application and subsamples of each were subjected to a single postharvest packing line spray application per Table 3.1. All samples were frozen stored up to 196 days (296 days for 2 samples) and then analyzed by HPLC/UV for fenhexamid residues. The maximum residue reported: in sweet cherries treated only by preharvest application was 1.2 ppm (per §5.14, **1.8 ppm** in sweet cherry and **4.9 ppm** in tart cherry); in field-untreated cherries treated only by postharvest application was 2.9 ppm; and in field-treated cherries also receiving a postharvest application was **3.8 ppm**. No data were submitted for tart cherry samples treated postharvest or for sweet cherry samples treated postharvest by fruit dip. The lack of data on tart cherries is not of concern since about 94% of that crop is frozen, canned, processed into juice or wine, and candied or dried into snack food ("Food and Feed Crops of the United States", Second Edition, G.M. Markle, J.J. Baron, and B.A. Schneider, 1998) and would be unlikely to receive postharvest fungicide treatments. It is noted that in these 4 trials only the two late season preharvest applications were made (and the two earlier season ones also permitted by the proposed label were omitted). However, in the 6 field trials previously submitted (see §5.14), all four preharvest applications were made, per the proposed label. See **§5.18** for discussion of appropriate tolerance level.

Stone Fruit - Appropriate Tolerance Level(s)

5.18 The petitioner is proposing a **10.0 ppm** tolerance for stone fruit, group 8. This level is appropriate for peach and cherry (sweet and tart), i.e., "stone fruit, group 8, except plum, fresh prune". Since the maximum residue in plum (fresh prune) is >5x lower than in peach and cherry, a separate tolerance entry continues to be appropriate for "plum, fresh prune" and the appropriate tolerance level is **1.5**

ppm. A **revised Section F** reflecting this nomenclature and tolerance levels should be submitted.

Leafy Greens - Head and Leaf Lettuce (subgroup 4A, except spinach)

5.19 Supervised residue trials (4 head, 4 leaf) were conducted in Europe with **greenhouse-grown lettuce**. In each trial, lettuce plants were treated twice with Teldor 50 WG (equivalent to Elevate 50 WDG) at 0.67 lb ai/A for a seasonal total of 1.34 lbs ai/A. Samples were harvested at PHIs of 0-7 (or 10) days and frozen stored (≤297 days) prior to analysis by HPLC/UV for fenhexamid residues. Residues in head lettuce ranged from 1.3-23 ppm, with the maximum residue at a 3-day PHI being **21 ppm**. Residues in leaf lettuce ranged from 2.3-23 ppm, with the maximum residue at a 3-day PHI being **23 ppm**. These data represent **0.89x** the maximum seasonal total of 1.5 lbs ai/A allowed by the proposed labeling. Since the label use is limited to the carefully controlled growing conditions of a greenhouse, the data are considered sufficient to support the proposed tolerance of **30.0 ppm** for "leafy greens subgroup 4A, except spinach" (no data were submitted for spinach) in conjunction with the proposed label use with a 3-day PHI.

Cilantro (member of subgroup 4A)

5.20 No field trial data were submitted for **cilantro**. Per the 6/14/02 Amended Commodity Definitions memo of B. Schneider, Item IV, parsley is now redefined in 40 CFR 180,1(h) as including parsley and cilantro (fresh leaves). Parsley is a member of the leafy greens subgroup 4A and field trials for the representative crops, head and leaf lettuce, have been submitted. The petitioner intends the same use pattern for both leafy greens and fresh cilantro. The tolerance on "cilantro, leaves" should be established at the same level (**30.0 ppm**) as that for subgroup 4A. Until a Federal Register Notice is issued revising 40 CFR 180.1(h), "cilantro, leaves" should be listed as a separate entry in 40 CFR 180.553 and on the registered label. A **revised Section F** listing cilantro leaves is needed.

Cucumber

5.21 Eight supervised residue trials were conducted in Europe on **greenhouse-grown cucumbers**. In each trial, cucumber plants were treated three times with KBR 2738 50WG (equivalent to Elevate 50 WDG) at 0.67 lb ai/A, for a seasonal total of 2.0 lbs ai/A. Samples were harvested at PHIs of 0-3 (or 7) days and frozen stored (≤ 274 days) until analysis by HPLC/UV for fenhexamid residues. Residues ranged from <0.05 ppm (7-day PHI) to **1.0 ppm** (0-day PHI). Although these data represent only **0.67x** the maximum seasonal total of 3.0 lbs ai/A allowed by the proposed labeling, since the label use is limited to the carefully controlled growing conditions of a greenhouse, the data are considered sufficient to support the proposed tolerance of **2.0 ppm** for cucumber in conjunction with the proposed label use with a 0-day PHI.

Fruiting Vegetable - Pepper (representative crop of group 8)

5.22 Supervised residue trials (9) were conducted in Europe with **greenhouse-grown bell pepper** plants. In each trial, bell pepper plants were treated three times with KBR 2738 50 WG at 0.67 lb ai/A, for a seasonal total of 2.0 lbs ai/A. Samples were harvested at PHIs of 0-3 (or 7) days and frozen stored (≤157 days) prior to analysis by HPLC/UV for fenhexamid residues. Residues ranged from 0.20 ppm (7-day PHI) to **1.1 ppm** (0-day PHI). Although these data represent only **0.67x** the maximum seasonal total of 3.0 lbs

ai/A allowed by the proposed labeling, since the label use is limited to the carefully controlled growing conditions of a greenhouse, the data are considered sufficient to support a tolerance of **2.0 ppm** for "fruiting vegetables, group 8, except non-bell peppers" in conjunction with the proposed label use with a 0-day PHI. A revised Section F is needed which excludes non-bell peppers from the crop group tolerance. For use on non-bell peppers three greenhouse residue trials reflecting the proposed label directions (1x seasonal rate) are required.

Fruiting Vegetable - Tomato (representative crop of group 8)

5.23 Supervised residue trials (8) were conducted in Europe with **greenhouse-grown tomato** plants. In each trial, tomato plants were treated three times with KBR 2738 50WG at 0.67 lb ai/A, for a seasonal total of 2.0 lbs ai/A. Samples were harvested at PHIs of 0-3 (or 7) days and frozen stored (≤164 days) prior to analysis by HPLC/UV for fenhexamid residues. Residues ranged from 0.23 ppm (7-day PHI) to **1.2 ppm** (1-day PHI). The maximum residue at 0-day PHI was 0.85 ppm. Although these data represent only **0.67x** the maximum seasonal total of 3.0 lbs ai/A allowed by the proposed labeling, since the label use is limited to the carefully controlled growing conditions of a greenhouse, the data are considered sufficient to support a tolerance of **2.0 ppm** for "fruiting vegetables, group 8, except non-bell peppers" in conjunction with the proposed label use with a 0-day PHI

Fruiting Vegetable - Transplant Production

5.24 **Transplant Production Uses**. IR-4 conducted magnitude of the residue studies with tomatoes and peppers, based on a use pattern of up to 4 applications of Elevate 50 WDG applied to transplants (prior to transplanting into the field) in a spray solution of up to 2.0 lbs ai/100 gal applied to runoff. Analysis of the tomatoes and peppers sprayed at the above-mentioned application rate and 5X that application rate (tomato) indicated **no detectable residues** (Lowest Level of Method Validation = 0.02 ppm). (Information contained in an e:mail dated 3/4/03 from Johannes Corley, Associate Coordinator, IR-4). Based on these data, the transplant use (per Table 3.1) is a negligible contributor to the proposed tolerance (2 ppm) on fruiting vegetables.

OPPTS GLN 860.1520: Processed Food/Feed

5.25 The original tolerances for fresh and dried plums (prunes) were established in conjunction with PP# 7F4890 (D254137, 2/02/00, M. Nelson). In the absence of a plum processing study, the tolerance on dried prunes was based upon the highest average field trial (HAFT) residue value for plums (fresh prunes) multiplied by the theoretical maximum concentration factor (TMCF) for dried prunes (3.4x), appropriately rounded. In the continued absence of a plum processing study, the appropriate tolerance on dried prunes, based on the residue data from preharvest and postharvest application in subject petition 2E6496, is 0.645 ppm (HAFT) x 3.4 (TMCF) = 2.2 ppm, rounded up to 2.5 ppm. A **revised Section F** proposing a **2.5 ppm** tolerance for "plum, prune, dried" should be submitted. Alternatively, the petitioner may opt to conduct/submit a plum processing study as a condition of registration.

5.26 A tomato processing study was not submitted and is not required in support of the currently proposed label uses on tomatoes since greenhouse-grown tomatoes would not be expected to be diverted to processing, and since treated transplants reportedly contained no detectable residue even when treated at a 10 lbs ai/100 gal spray rate (ca 13x the proposed rate).

OPPTS GLN 860.1850 and 860.1900: Confined/Field Accumulation in Rotational Crops

5.27 A fenhexamid confined rotational crop study has previously been submitted and reviewed (D244844 & D249061, 3/25/99, G. Herndon). In that study, a single application of the proposed fenhexamid formulation was made to bare soil prior to planting representative rotational crops at 3.09 lbs ai/A (1x). Fenhexamid was only detected at levels >0.01 ppm in/on Swiss chard (max. 0.03 ppm) at the 30-day plantback interval. Residues were <0.01 ppm in/on other rotational crop commodities: turnips (tops, roots) and wheat (forage, hay, straw, and grain). HED concluded that a 30-day plantback interval should appear on the label and apply to all crops without a registered use. The Elevate 50 WDG registered label does specify a 30-day plantback restriction for non-label crops.

International Harmonization

5.28 No Codex or Mexican maximum residue limits (MRLs) are established for residues of fenhexamid. Canadian MRLs are currently established for fenhexamid in raisins (6 ppm), grapes (4 ppm), and strawberries (3 ppm). These levels (and the tolerance expression) are in harmony with the US tolerances established for fenhexamid residues on these commodities. Canadian MRL's are also established on stone fruit at levels which match the current U.S. tolerances for preharvest use (0.5 ppm on plum and 6.0 ppm on the rest). With the requested addition of postharvest uses, the U.S. tolerances will need to be raised beyond the Canadian MRL's.

6.0 RECOMMENDATIONS

Contingent upon submission of a revised Section F (per Conclusions 5.18, 5.20, 5.22 and 5.25) and an acceptable human health risk assessment, HED has no objection to the establishment of tolerances for residues of fenhexamid in/on:

Kiwifruit	15.0 ppm
Vegetable, fruiting, group 8, except non-bell peppers	2.0 ppm
Cucumber	2.0 ppm
Leafy greens, subgroup 4A, except spinach	30.0 ppm
Cilantro, leaves	30.0 ppm
Fruit, stone, group 12, except plum, prune, fresh	10.0 ppm
Plum, prune, dried	2.5 ppm
Plum, prune, fresh	1.5 ppm

If use is desired on non-bell peppers, the petitioner is requested to conduct 3 greenhouse residue trials on non-bell peppers per the proposed label use directions. The petitioner also has the option to conduct/submit a processing study for plum (fresh prune); if sample storage exceeds 1 month prior to residue analysis, freezer storage stability data for the duration of the storage period would also need to be generated/provided.

[Note to PM: The above-listed tolerances for stone fruit and plum are to replace those currently in 40 CFR 180.553 .]

7.0 ATTACHMENTS (3):

IRL Codex Status Sheet	Dated 07-15-03
DER for Crop Residue Studies	MRID 45682001 (et al.) - de1
DER for Storage Stability Studies	MRID 45682001 (et al.) - de2

8.0 DISTRIBUTION

cc WITH Attachments: **M. Nelson, RAB2 Reading File**

INTERNATIONAL RESIDUE LIMIT STATUS

Chemical Name: N-(2,3-dichloro-4-hydroxyphenyl)-1-methyl-cyclohexanecarboxamide	Common Name: Fenhexamid	☒ Proposed tolerance ☐ Reevaluated tolerance ☐ Other	Date: 07-15-2003

Codex Status (Maximum Residue Limits)

☒ No Codex proposal step 6 or above
☐ No Codex proposal step 6 or above for the crops requested

Residue definition (step 8/CXL): N/A

Crop (s)	MRL (mg/kg)

U. S. Tolerances

Petition Number: 2E6463, et al.
DP Barcode: D285209 et al.
Other Identifier: PC Code 090209

Reviewer/Branch: **M. Nelson/RAB2**

Residue definition: per 40 CFR 180.553

Crop(s)	Tolerance (ppm)
Kiwifruit	15.0 ppm
Vegetable, fruiting, group 8 except non-bell peppers	2.0 ppm
Cucumber	2.0 ppm
Leafy greens, subgroup 4A, except spinach	30.0 ppm
Cilantro, leaves	30.0 ppm
Fruit, stone, group 12, except plum, prune, fresh	10.0 ppm
Plum, prune, dried	2.5 ppm
Plum, prune, fresh	1.5 ppm

Maximum Residue Limits for Canada

☐ No Limits
☒ No Limits for the crops requested

Residue definition:

Crop(s)	MRL (mg/kg)
Stone fruit exc plums	6.0
Plums	0.5
Grapes	4.0

Maximum Residue Limits for Mexico

☒ No Limits
☐ No Limits for the crops requested

Residue definition:

Crop(s)	MRL (mg/kg)

Raisins	6.0		
Notes/Special Instructions: **S. Funk, 07/15/03**			

Primary Evaluator:	Chang Sook Lee Peoples AERS, CDPR	Date: 5/14/03	
Peer Reviewers:	MNelson, Chemist RAB2/HED (7509C)	Date: 7/03/03	
	Richard A. Loranger, Sr Scientist RAB2/HED (7509C)	Date: 12/02/03	

STUDY REPORTS:

MRID No. 45682001, David C. Thompson, Ph.D. (March 27, 2002), Fenhexamid: Magnitude of the Residue on Kiwifruit, IR-4 Project, Lab Project Number IR-4 PR No. 07600, Unpublished, 228 Pages.

MRID No. 45821101, David C. Thompson, Ph.D. and Hong Chen, Ph.D. (December 4, 2002), Fenhexamid: Magnitude of the Residue on Fresh Market Plum Following Field and Post-Harvest Treatment, IR-4 Project, Lab Project Number IR-4 No 07318, Unpublished, 136 Pages.

MRID No. 45821102, David C. Thompson, Ph.D and Hong Chen, Ph.D. (December 4, 2002), Fenhexamid: Magnitude of the Residue on Fresh Market Peach Following Field and Post-Harvest Treatment, IR-4 Project, Lab Project Number IR-4 No 06936, Unpublished, 160 Pages.

MRID No. 45821103, David C. Thompson, Ph.D. and Hong Chen, Ph.D. (December 4, 2002), Fenhexamid: Magnitude of the Residue on Fresh Market Cherry Following Field and Post-Harvest Treatment, IR-4 Project, Lab Project Number IR-4 No. 06937, Unpublished, 171 Pages.

MRID No. 45795601, Dr. F. Nußlein (July 9, 2002), Determination of Residues of Teldor (50WG) in/on Lettuce Following Spray Application in the Greenhouse in Germany and Italy, Bayer AG, Project ID RA-2068/01, Unpublished, 43 Pages.

MRID No. 45817101, Dr. F. Nußlein (February 14, 2002), Determination of Residues of KBR 2738 after Spray Application of Teldor 50 WG on Lettuce in the Greenhouse in Germany and Italy, Bayer AG, Project ID RA-2032/00, Unpublished, 39 Pages.

MRID No. 45736603, Dr. F. Nußlein. (November 11, 1998), Fenhexamid: Magnitude of the Residue on Cucumber (Greenhouse) in Benelux, Italy, Greece and Spain, IR-4 Project, Project ID RA-2026/97, Unpublished, 51 Pages.

MRID No.45736604, Dr. F. Nußlein and Dr. H. Block (October 20, 1999), Determination of Residues of KBR 2738 50WG Following Spray Application in the Greenhouse in/on Cucumber in Belgium, Italy, Spain and Germany, IR-4 Project, Project ID RA-2015/98, Unpublished 41 Pages.

MRID No. 45736605, Dr. F. Nußlein (March 23, 1999), Determination of Residues of KBR 2738 (50 WG) on Pepper in the Greenhouse in Netherlands, France, Italy, and Spain, IR-4 Project, Project ID RA-2027/97, Unpublished 53 Pages.

MRID No. 45736606, Dr. K. Spiegel and Dr. A. Neigl (April 17, 2000), Determination of Residues of KBR 2738 on Pepper after Spray Application of KBR 2738 50Wg and 500 sc in the Greenhouse In Italy, Portugal, and France, IR-4 Project, Project ID RA-2094/99, Unpublished, 42 Pages.

MRID No. 45736601, Dr. F. Nußlein (August 6, 1996), Determination of Residues of KBR2738 50 WG on Tomato in France and Italy, IR-4 Project, Project ID RA-2060/95, Unpublished 38 Pages.

MRID No. 45736602, Dr. F. Nußlein (November 26, 1996), Determination of Residues of KBR 2738 (50 WG) in Tomato in the Federal Republic of Germany, Italy, Belgium and Greece, Unpublished, 50 Pages.

EXECUTIVE SUMMARY:

As part of a joint review project, this Data Evaluation Record (DER) was prepared by the California Department of Pesticide Regulation (CDPR) and was peer-reviewed by RAB2/HED.

Supervised residue trials (3) were conducted in CA (2) and OR (1) with kiwifruit (PP# 2E6463) treated ONLY by a single postharvest application of TM-402 50% WDG (equivalent to Elevate 50 WDG) as a packing line spray (CA) or as a 30 second dip treatment (CA, OR). The packing line spray was applied at a rate of approximately 0.75 lb ai/200,000 lb fruit in 8 to 20 gallons of water (low volume). The fruit dip was a solution of approximately 0.75 lb ai/100 gal of water. Samples were frozen stored up to 151 days prior to analysis by HPLC/UV for fenhexamid residues. Residues of fenhexamid ranged from 2.5 to 7.1 ppm in samples treated with the packing line spray, and from 6.5 to 12.5 ppm in samples that were dipped.

Supervised residue trials (2) on plum (fresh prune) (PP#3E6541) were conducted in CA to support combined preharvest and postharvest uses. A preharvest use is currently registered. Each of the two field trial sites consisted of one untreated control plot and one treated plot. Each treated plot received two foliar-directed applications of TM-402 50% WDG, 50% ai, at a rate of 0.75 lb ai/A, for a total of 1.50 lb ai/A. The applications were made 7 days apart. Untreated and treated

mature plum fruit were collected on the day of the second field application and subsamples of each were subjected to a postharvest treatment using either a packing line spray or a 30 second dip. The packing line spray application was conducted at a rate of 0.75 lb ai/200,000 lb fruit in either a low volume (7 gallons) or high volume (100 gallons) of water. The dip application was conducted at a rate of 0.75 lb ai/100 gal. The adjuvant Decco Lustr 251 was included in the tank mixes. All samples were frozen stored for up to 231 days and then analyzed by HPLC/UV for fenhexamid residues. The maximum residue reported: in plums treated only by preharvest application was <0.10 ppm; in field-untreated plums treated only by postharvest packing line spray was 0.42 ppm; in field-untreated plums treated only by postharvest dip was 0.71 ppm; in field-treated plums also receiving a postharvest packing line spray was 0.40 ppm; and in field-treated plums also receiving a postharvest dip application was 0.66 ppm. A residue decline study was not conducted with plum.

Supervised residue trials (3) were conducted with peach (PP#3E6541) in NJ, NC and CA to support combined preharvest and postharvest uses. A preharvest use is currently registered. In each trial, peach trees in the treated plot received two applications of TM-402 50% WDG, 50% a.i., at 0.75 lb a.i./A. Applications were made one week apart. Untreated and treated mature peach fruit were collected on the day of the second field application and subsamples of each were subjected to a post-harvest treatment using either a packing line spray or a 30 second dip. The packing line spray application was applied at a rate of approximately 0.75 lb ai/200,000 lb fruit in either a low volume (25 gallons) or high volume (100 gallons) of water. The dip application rate was approximately 0.75 lb ai/100 gal. The adjuvant Decco Lustr 251 was included in the tank mixes. All samples were frozen stored for up to 218 days and then analyzed by HPLC/UV for fenhexamid residues. The maximum residue reported: in peaches treated only by preharvest application was 2.1 ppm; in field-untreated peaches treated only by postharvest packing line spray was 4.2 ppm; in field-untreated peaches treated only by postharvest dip was 6.6 ppm; in field-treated peaches also receiving a postharvest packing line spray was 4.4 ppm; and in field-treated peaches also receiving a postharvest dip application was 7.2 ppm. A residue decline study was not conducted with peaches.

Supervised residue trials (4) on sweet cherry (PP#3E6541) were conducted in WA (2), MI and CA to support combined preharvest and postharvest uses. A preharvest use is currently registered. In each trial, cherry trees in the treated plot received two foliar-directed sprays at a 7-day retreatment interval of TM-402 50% WDG, 50% a.i., at 0.75lb a.i./A, which corresponds to the currently registered Elevate 50 WDG label maximum application rate on stone fruit. Untreated and treated mature cherry fruit were collected on the day of the second field application and subsamples of each were subjected to a single postharvest packing line spray application at a rate of 0.75 lb ai/25,000 lb fruit in 100 gallons (high volume) of water. The adjuvant Decco Lustr 251 was included in the tank mixes. All samples were frozen stored up to 196 days (296 days for 2 samples) and then analyzed by HPLC/UV for fenhexamid residues. The maximum residue reported: in cherries treated only by preharvest application was 1.2 ppm; in field-untreated cherries treated only by postharvest application was 2.9 ppm; and in field-treated cherries also receiving a postharvest application was 3.8 ppm. No data were submitted for tart cherry samples treated postharvest or for sweet cherry samples treated postharvest by fruit dip. A residue decline study was not conducted with cherry.

Supervised residue trials (4 head, 4 leaf) were conducted in Germany and Italy with greenhouse-grown lettuce (PP# 3E6532). In each trial, lettuce plants were treated twice with Teldor 50 WG (equivalent to Elevate 50 WDG), 50% ai, at 0.67 lb ai/A (0.75 kg ai/ha) for a seasonal total of 1.34 lb ai/A. Samples were harvested at PHIs of 0-7 (or 10) days to observe residue decline. Samples were frozen stored up to 297 days prior to analysis by HPLC/UV for fenhexamid residues. Residues in head lettuce ranged from 1.3-23 ppm, with the maximum residue at a 3-day PHI being 21 ppm. Residues in leaf lettuce ranged from 2.3-23 ppm, with the maximum residue at a 3-day PHI being 23 ppm.

Supervised residue trials (8) were conducted in Benelux, Italy (2), Greece, Spain (2), Belgium, and Germany with greenhouse-grown cucumber plants (PP#2E6496). In each trial, cucumber plants were treated three times with KBR 2738 (50WG), 50% ai, (equivalent to Elevate 50 WDG) at 0.67 lb ai/A (0.75 kg ai/ha), for a seasonal total of 2.0 lb ai/A. Samples were harvested at PHIs of 0-3 (or 7) days to observe residue decline. Samples were frozen stored up to 274 days prior to analysis by HPLC/UV for fenhexamid residues. Residues ranged from <0.05 ppm (7-day PHI) to 1.0 ppm (0-day PHI).

Supervised residue trials (9) were conducted in the Netherlands (2), France (2), Italy (3), Spain, and Portugal with greenhouse-grown bell pepper plants (PP#2E6496). Pepper plants were treated three times with KBR 2738 (50WG), 50% ai, at 0.67 lb ai/A (0.75 kg ai/ha), for a seasonal total of 2.0 lb ai/A. Samples were harvested at PHIs of 0-3 (or 7) days to observe residue decline. Samples were frozen stored up to 157 days prior to analysis by HPLC/UV for fenhexamid residues. Residues ranged from 0.20 ppm (7-day PHI) to 1.1 ppm (0-day PHI).

Supervised residue trials (8) were conducted in France (2), Italy (3), Germany, Belgium, and Greece with greenhouse-grown tomato plants (PP#2E6496). In each trial, tomato plants were treated three times with KBR 2738 (50WG), 50% ai, at 0.67 lb ai/A (0.75 kg ai/ha), for a seasonal total of 2.0 lb ai/A. Samples were harvested at PHIs of 0-3 (or 7) days to observe residue decline. Samples were frozen stored up to 164 days prior to analysis by HPLC/UV for fenhexamid residues. Residues ranged from 0.23 ppm (7-day PHI) to 1.2 ppm (1-day PHI). The maximum residue at 0-day PHI was 0.85 ppm.

Bayer AG "Method for determination of KBR 2738 (TM-402) residues in plant material by HPLC", J. Bachmann and F. Nublein, dated 6-16-95, was used to determine residues of fenhexamid per se. Adequate concurrent recoveries were obtained for kiwi (86-120% for 0.1 ppm spikes), plum (82-120% for 0.1-10 ppm), sweet cherry (96-110% for 1.0 ppm), lettuce (60-105% for 0.05-10 ppm), peach (90-110% for 1.0-10 ppm), cucumber (63-82% for 0.05-5.0 ppm), pepper (73-103% for 0.05-5.0 ppm) and tomato (79-99% for 0.05-0.5 ppm).

The numbers of trials for all the above crops are adequate to represent postharvest or greenhouse uses. Frozen storage stability studies on kiwi, peaches, cherries, and tomatoes are reviewed in a companion DER (of MRIDs 45682001, 45821102, 45821103, 45736601, and 45736602). The storage stability data support all of the above field trial data.

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Under the conditions and parameters used in the study, the field trial residue data are classified as scientifically acceptable, with the following comments:

1. Supporting data such as soil characteristics, weather, cultural practice data, irrigation, and maintenance chemical applications were not collected in strict adherence to 40 CFR 160 guidelines.

2. In one sweet cherry field trial, two samples (1 control and 1 pre-harvest) were stored longer (296 days) than the storage period of the cherry storage stability study (216 days), however this would not affect the conclusions of the studies.

3. The number of preharvest applications (two, totaling 1.5 lb ai/A) made in these stone fruit residue studies was less than the maximum number (four, totaling 3.0 lb ai/A) currently registered. However, this should not have much, if any, impact on the outcome since the two omitted applications were both early season, and the two applications which were made were at fruiting and harvest (0-day PHI).

4. The lettuce, cucumber, pepper and tomato studies were conducted in Europe only. Since these studies were conducted in greenhouses, and to support greenhouse use only, it is presumed that growing conditions would be similar whether in Europe or the United States.

5. The number of tomato and lettuce field trials submitted were fewer than the number of field trials required by OPPTS 860.1500 (see Table B 1.3). However, since the use is for greenhouse and transplant production use only, the number of submitted trials is deemed sufficient.

6. All the submitted pepper trials (9) were conducted on bell peppers.

7. Summary, rather than individual, concurrent recovery data were provided with the European (lettuce, cucumber, pepper and tomato) greenhouse residue studies.

COMPLIANCE:

Signed and dated GLP, Quality Assurance and Data Confidentiality statements were provided. There were minor deviations from regulatory requirements; however, these deviations do not affect the conclusions of the

studies.

A. BACKGROUND INFORMATION

The active ingredient in ELEVATE, fenhexamid, prevents fungi from infecting plants by inhibiting germ tube elongation, mycelial growth and spore germination. As a locally systemic protectant fungicide, ELEVATE is absorbed into the waxy layer of the cuticle and is protected from being washed-off. This ensures strong, long-lasting protective activity and optimal disease control, even when exposed to rainfall or irrigation.

ELEVATE is effective in controlling *Botrytis cinerea*, *Monolinia* (brown rot / blossom blight / twig blight) and has been shown to suppress *Uncinula necator* (powdery mildew). It also provides post-infection activity when applied early in the disease life cycle.

TABLE A.1. Test Compound Nomenclature

Compound	Chemical Structure
Common name	Fenhexamid
Company experimental name	KBR 2738
IUPAC name	2,3-dichloro-4-(1-methylcyclohexyl-carbonylamine)-phenol
CAS name	N-(2,3-dichloro-4-hydroxyphenyl)-1-methyl-cyclohexanecarboxamide
CAS #	126833-17-8
End-use product/EP	ELEVATE 50 WDG Fungicide, EPA Reg. No. 66330-35

TABLE A.2. Physicochemical Properties of the Technical Grade Test Compound

Parameter	Value	Reference
Melting point/range	153 °C	Fenhexamid: Pesticide Fact Sheet (May 20, 1999) Fenhexamid (KBR 2738)-a Botryticide from a New Chemical Class, Pflanzenschutz-Nachrichten Bayer 52/1999, 2
pH	8.3 in 1% solution of water	
Density	1.34 g/ml @ 20 °C	
Water solubility (20 °C)	20 mg/l	
Solvent solubility (mg/L at 20 °C)	dichloromethane: 31000, 2-propanol: 91000, n-hexane: < 100, Toluene: 5700	

Vapor pressure at 25 °C	$7x10^{-9}$ Torr	
Dissociation constant (pK_a)	7.3	
Octanol/water partition coefficient Log(K_{OW})	3.51 (pH 7, 20 °C)	
UV/visible absorption spectrum	245 and 290 nm	See previous page

B. EXPERIMENTAL DESIGN

B.1. Study Site Information

TABLE B.1.1Soil Characterization.

Trial Identifier (City, State/Year)	Soil characteristics			
	Type	%OM	pH	CEC
Kiwifruit				
Farmersville, CA / 00-CA57	Fine sandy loam	N/A[1]	N/A[1]	N/A[1]
Parlier, CA / 00-CA58	Sandy loam	N/A[1]	N/A[1]	N/A[1]
Brooks, OR / 00-OR08	Silt loam	N/A[1]	N/A[1]	N/A[1]
Plum				
Parlier, CA/ 00-CA54	Sandy loam	N/A[1]	7	N/A[1]
Parlier, CA / 00-CA55	Sandy loam	N/A[1]	7	N/A[1]
Peach				
Bridgeton, NJ / 00-NJ32	Aura sandy loam	2.1	5.4	N/A[1]
Raleigh, NC / 00-NC22	Sand	1.2	6.6	N/A[1]
Riverside, CA / 00-CA53	Sandy loam	2.0	7.0	N/A[1]
Cherry (sweet)				
Prosser, WA / 00-WA33	Silt loam	1.03	7.2	N/A[1]
Prosser, WA / 00-WA34	Sandy loam	1.15	8.0	N/A[1]
Traverse City, MI / 00-MI15	Loamy sand	N/A[1]	6.5	N/A[1]
Stockton, CA / 00-CA52	Clay loam	1.0	6.8	N/A[1]
Lettuce (Greenhouse)				
Germany, VG08 R 2001 0167/8	Sandy loam	N/A[1]	6.4	N/A[1]
Italy, IT14 / R 2001 0168/6	Sandy silt	0.8	7.8	N/A[1]

Italy, IT19 / R 2001 0169/4	Sand	0.3	7.7	N/A[1]
Germany, VG08 R 2001 0170/8	Sandy loam	N/A[1]	6.3	N/A[1]
Germany, VG08 R 2000 0260/2	Sandy loam	N/A[1]	6.5	N/A[1]
Italy, IT19 / R 2000 0261/0	Sand	2.0	7.8	N/A[1]
Germany, VG08 R 2000 0262/9	Sandy loam	N/A[1]	6.3	N/A[1]
Italy, IT15 / R 2000 0263/7	Sand	1.7	7.5	N/A[1]
Cucumber (Greenhouse)				
Duffel, Benelux (700215)	Artificial medium	N/A[1]	N/A[1]	N/A[1]
Imola, Italy (703133)	Loamy clay	1.73	8.19	N/A[1]
Alexandria, Greece (703141)	Sandy clay	2.2	6.5	N/A[1]
Vicar, Spain (703168)	Artificial medium	N/A[1]	N/A[1]	N/A[1]
Belgium (810053)	Rock Wool	N/A[1]	N/A[1]	N/A[1]
Germany (813257)	Loamy sand	N/A[1]	6.4	N/A[1]
Italy (813265)	Silty loam	2.2	7.3	N/A[1]
Spain (813273)	Loamy sand	0.84	6.9	N/A[1]
Pepper (Greenhouse)				
Netherlands (700258)	Artificial medium	N/A[1]	6.2	N/A[1]
France (703176)	N/A[1]	N/A[1]	N/A[1]	N/A[1]
Italy (703184)	Loamy sand	0.8	8.3	N/A[1]
Spain (703192)	Sandy clay	N/A[1]	N/A[1]	N/A[1]
Netherlands (708038)	Artificial medium	N/A[1]	6.5	N/A[1]
Portugal (R1999 0314/6)	Sand	N/A[1]	N/A[1]	N/A[1]
Italy (R1999 0315/4)	Sand	1.3	7.3	N/A[1]
France (R1999 0316/2)	Silty clay	1.3	8.0	N/A[1]
Italy (R1999 0532/7)	Sand	1.3	7.3	N/A[1]
Tomato (Greenhouse)				
France (501646)	N/A	N/A[1]	N/A[1]	N/A[1]
Italy (501654)	Sand	0.4	7.8	N/A[1]
France (505307)	N/A	N/A[1]	N/A[1]	N/A[1]

Italy (505323)	Sand	2.1	7.6	N/A[1]
Germany (600466)	Loamy sand	N/A[1]	6.4	N/A[1]
Italy (600512)	Sand	1.4	7.26	N/A[1]
Belgium (604615)	Loam	N/A[1]	N/A[1]	N/A[1]
Greece (604631)	Artificial medium	N/A[1]	N/A[1]	N/A[1]

[1] N/A - Not available

TABLE B.1.2. Study Use Pattern.

Trial ID (City, State/Year)	EP[1]	Application					Tank Mix Adjuvants	Harvest Procedures
		Treat. No. and Crop Stage at Application	Rate, lb ai/A	RTI[2] (days)	Method	Total Rate lb ai/A		

Primary Evaluator:	Chang Sook Lee Peoples AERS, CDPR	Date: 5/14/03	
Peer Reviewers:	M. Nelson, Chemist RAB2/HED (7509C)	Date: 7/01/03	
	R. A. Loranger, Sr Scientist RAB2/HED (7509C)	Date: 12/02/03	

STUDY REPORTS:

MRID No. 45682001, David C. Thompson, Ph.D. (March 27, 2002), Fenhexamid: Magnitude of the Residue on Kiwifruit, IR-4 Project, Lab Project Number IR-4 PR No. 07600, Unpublished, 228 Pages.

MRID No. 45821102, David C. Thompson, Ph.D and Hong Chen, Ph.D. (December 4, 2002), Fenhexamid: Magnitude of the Residue on Fresh Market Peach Following Field and Post-Harvest Treatment, IR-4 Project, Lab Project Number IR-4 No 06936, Unpublished, 160 Pages.

MRID No. 45821103, David C. Thompson, Ph.D. and Hong Chen, Ph.D. (December 4, 2002), Fenhexamid: Magnitude of the Residue on Fresh Market Cherry Following field and Post-Harvest Treatment, IR-4 Project, Lab Project Number IR-4 No. 06937, Unpublished, 171 Pages.

MRID No. 45736601, Dr. F. Nußlein (August 6, 1996), Determination of Residues of KBR2738 50 WG on Tomato in France and Italy, IR-4 Project, Project ID RA-2060/95, Unpublished 38 Pages.

MRID No. 45736602, Dr. F. Nußlein (November 26, 1996), Determination of Residues of KBR 2738 (50 WG) in Tomato in the Federal Republic of Germany, Italy, Belgium and Greece, Unpublished, 50 Pages.

EXECUTIVE SUMMARY:

As part of a joint review project, this Data Evaluation Record (DER) was prepared by the California Department of Pesticide Regulation (CDPR) and was peer-reviewed by RAB2/HED.

This storage stability study with kiwifruit (PP#2E6463) was conducted in support of the fenhexamid/kiwifruit residue study (reviewed in the DER of MRID 45682001) in which samples were frozen stored 151 days prior to analysis. Chopped kiwifruit samples from untreated controls were fortified with 5.0 ppm fenhexamid and stored in a freezer at < -20 °C for 145

days. Stored samples were then analyzed by HPLC/UV for residues of fenhexamid. Recoveries ranged from 90 to 92 %.

This storage stability study with peaches (PP# 3E6541) was conducted in support of the fenhexamid residue study (reviewed in the DER of MRIDs 45821101 & 45821102) in which samples of peaches and plums were frozen stored 218 and 231 days, respectively, prior to analysis. Chopped peach samples from untreated controls were fortified with 5.0 ppm fenhexamid and stored in a freezer at -21±7 °C for 221-223 days. Stored samples were then analyzed by HPLC/UV for residues of fenhexamid. Recoveries ranged from 76 to 84%.

This storage stability study with sweet cherries (also PP#3E6541) was conducted in support of the fenhexamid residue study (reviewed in the DER of MRID 45821103) in which most cherry samples were frozen stored ≤196 days (two samples were stored 296 days) prior to analysis. Chopped cherry samples from untreated controls were fortified with 5.0 ppm fenhexamid and stored in a freezer at –37.2 to –8.5 °C for 216 days. Stored samples were then analyzed by HPLC/UV for residues of fenhexamid. Recoveries ranged from 76 to 82%.

This storage stability study with tomatoes (PP#2E6496) was conducted in support of the fenhexamid /tomato, pepper, lettuce and cucumber crop residue studies (reviewed in the DER of MRIDs 45736601/45736602, 45736605/45736606, 45795601/45817101, and 45736603/45736604) in which samples were frozen stored up to 164, 157, 297, and 274 days, respectively, prior to analysis. Chopped tomato samples from untreated controls were fortified with 0.5 ppm fenhexamid and frozen stored at < -18 °C for 365 days. Stored samples were then analyzed by HPLC/UV for residues of fenhexamid. Recoveries were reported as "comparable to method suitability recoveries". (In the tomato residue studies, concurrent recoveries ranged from 79-99%, n=17, at the 0.5 ppm fortification level).

Bayer AG "Method for determination of KBR 2738 (TM-402) residues in plant material by HPLC", J. Bachmann and F. Nublein, dated 6-16-95, was used to determine residues of fenhexamid per se. Adequate concurrent recoveries were obtained for kiwi (86-120% for 0.1 ppm spikes), plum (82-120% for 0.1-10 ppm), sweet cherry (96-110% for 1.0 ppm), lettuce (60-105% for 0.05-10 ppm), peach (90-110% for 1.0-10 ppm), cucumber (63-82% for 0.05-5.0 ppm), pepper (73-103% for 0.05-5.0 ppm) and tomato (79-99% for 0.05-0.5 ppm).

The storage stability data for kiwifruit, peach, cherry, and tomato indicate that fenhexamid is stable on these crops under the conditions of the study.

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

The above-listed frozen storage stability studies are classified as acceptable, with the following comment:

1. Summary, rather than individual, storage stability data were provided with the tomato study.

COMPLIANCE:

Signed and dated GLP, Quality Assurance and Data Confidentiality statements were provided. There were minor deviations from regulatory requirements; however, these deviations do not affect the conclusions of the studies.

A. BACKGROUND INFORMATION

The active ingredient in ELEVATE, fenhexamid, prevents fungi from infecting plants by inhibiting germ tube elongation, mycelial growth and spore germination. As a locally systemic protectant fungicide, ELEVATE is absorbed into the waxy layer of the cuticle and is protected from being washed-off. This ensures strong, long-lasting protective activity and optimal disease control, even when exposed to rainfall or irrigation.

ELEVATE is effective in controlling *Botrytis cinerea*, *Monolinia* (brown rot / blossom blight / twig blight) and has been shown to suppress *Uncinula necator* (powdery mildew). It also provides post-infection activity when applied early in the disease life cycle.

TABLE A.1. Test Compound Nomenclature

Compound	Chemical Structure
Common name	Fenhexamid
Company experimental name	KBR 2738
IUPAC name	2,3-dichloro-4-(1-methylcyclohexyl-carbonylamine)-phenol
CAS name	N-(2,3-dichloro-4-hydroxyphenyl)-1-methyl-cyclohexanecarboxamide
CAS #	126833-17-8
End-use product/EP	ELEVATE 50 WDG Fungicide, EPA Reg. No. 66330-35

TABLE A.2. Physicochemical Properties of the Technical Grade Test Compound		
Parameter	Value	Reference
Melting point/range	153 °C	Fenhexamid: Pesticide Fact Sheet (May 20, 1999) Fenhexamid (KBR 2738)- a Botryticide from a New Chemical Class, Pflanzenschutz-Nachrichten Bayer 52/1999, 2
pH	8.3 in 1% solution of water	
Density	1.34 g/ml @ 20 °C	
Water solubility (20°C)	20 mg/l	
Solvent solubility (mg/L at 20°C)	dichloromethane: 31000, 2-propanol: 91000, n-hexane: < 100, Toluene: 5700	
Vapor pressure at 25°C	$7x10^{-9}$ Torr	
Dissociation constant (pK_a)	7.3	
Actinal/water partition coefficient Log(K_{OW})	3.51 (pH 7, 20 °C)	
UV/visible absorption spectrum	245 and 290 nm	

B. EXPERIMENTAL DESIGN

B.1. Sample Preparation

50 g portions of chopped kiwifruit from untreated controls were weighted and fortified with 0.5 ml of 500 ug/ml fenhexamid standard which was made with methanol solution. The resulting fortification level was 5.0 ppm. Fortified samples were stored in a freezer at < -20 °C and at the 145-day storage interval, storage stability study samples were analyzed.

50 g portions of chopped peach from untreated controls were weighted and fortified with 1.25 ml of 200 ug/ml fenhexamid standard which was made with methanol solution. The resulting fortification level was 5.0 ppm. Fortified samples were stored in a freezer at -21±7 °C. At the 221 to 223-day storage interval, storage stability study samples were analyzed.

50 g portions of chopped sweet cherry from untreated controls were weighted and fortified with 0.5 ml of 500 ug/ml fenhexamid standard which was made with methanol solution. The resulting fortification level was 5.0 ppm. Fortified samples were stored in a freezer at –37.2 to –8.5 °C. At the 214 to 216-day storage interval, storage stability study samples were analyzed.

Chopped tomato from untreated controls were weighted and fortified with fenhexamid standard at the 0.5 ppm level. The amended samples were stored in a freezer at < -18 °C. At the 365-day storage interval, storage stability study samples were analyzed.

B.2. Analytical Methodology

The Reference Method (Bayer AG method, "Method for determination of KBR 2738 (TM-402) residues in plant material by HPLC", J. Bachman and F. Nußlein, dated 6-16-95), was used for data collection for the determination of fenhexamid in raw agricultural commodities. Residues of fenhexamid were extracted with acetone and filtered. After evaporation of acetone the aqueous residue is cleaned up on a ChemElute column and eluted with cyclohexane / ethyl acetate (85/15). The sample is then evaporated to dryness and taken up in 100% methanol. The analyte was analyzed by HPLC equipped with an UV detector at 289 nm wavelength. The Limits of Quantification (LOQ) of 0.1 ppm for kiwifruit, peach and cherry and 0.05 ppm for tomato were reported. Adequate concurrent recoveries were obtained on kiwi, stone fruit, lettuce, cucumber, tomato, and pepper (see Table C.1)

C. RESULTS AND DISCUSSION

Control samples of each matrix were fortified with fenhexamid and analyzed both before and concurrently with field-treated samples. Method validation was accomplished by spiking untreated control samples; the lowest fortification level was at the LOQ for the particular matrix, except cherry and peach. The method validation and concurrent recoveries fell within the acceptable range of 70 to 120 % with few exceptions. Fortification levels, recovery ranges, and average recoveries are shown in Table C.1.

The maximum storage interval for kiwifruit samples from the residue study was 151 days (see separate field trial DER for MRID 45682001). Storage stability samples were fortified with 5.0 ppm of fenhexamid and held in frozen storage for 145 days. The recoveries for the storage stability samples ranged from 90 to 92%. The maximum storage interval for peach samples from the stone fruit residue study was 218 days. Storage stability samples were fortified with 5.0 ppm of fenhexamid and held in frozen storage for 221 to 223 days. The recoveries for the storage stability sample ranged from 76 to 84%. The maximum storage interval for sweet cherry samples from the stone fruit residue study was 296 days (most were stored ≤196 days)(see separate field trial DER for MRID 45682001). Storage stability samples were fortified with 5.0 ppm of fenhexamid and held in frozen storage for 214 to 216 days. The recoveries for the storage stability samples ranged from 76 to 82%. The maximum storage interval for tomato samples from the residue studies was 164 days (see separate field trial DER for MRID 45682001). Storage stability samples were fortified with 0.5 ppm of fenhexamid and held in frozen storage for 365 days. The recoveries for the storage stability samples were comparable to method suitability recoveries (see Table C.1). The storage stability data for kiwifruit, peach, cherry, and tomato (see Table C.2) indicate that fenhexamid is stable on these crops under the conditions of the study.

TABLE C.1. Summary of Concurrent Recoveries of Fenhexamid from Various Matrices.

Matrix	Analyte	Spike level (mg/kg)	Storage Interval (days)	Sample size (n)	Recoveries (%)	Mean ± std dev
Kiwifruit	Fenhexamid	0.1	151	3	86 - 120	102.0 ± 17.1
	Fenhexamid	0.1	231	5	90-120	104.4 ± 14.5
		1.0	231	5	89 – 100	94.8 ± 5.1
Plum		10	231	2	82 - 100	91
		1.0	218	10	90 - 110	98.5 ± 5.6
Peach	Fenhexamid	10	218	8	92 - 98	95.8 ± 2.2
Cherry, sweet	Fenhexamid	1.0	296	13	96 - 110	99.9 ± 3.4
		0.05	297	11	81 - 115	95.1 ± 11.4
		0.5	297	12	60 – 105	86.7 ± 14.3
		5.0	297	12	83 – 97	92.4 ± 4.5
Lettuce (head / leaf) (Greenhouse)	Fenhexamid	10.0	297	2	94, 96	95
		0.05	274	8	69 - 82	73.8 ± 5.3
		0.5	274	8	63 - 81	70.6 ± 6.2
Cucumber (Greenhouse)	Fenhexamid	5.0	274	5	73 - 75	73.8 ± 0.8
		0.05	157	8	86 - 97	91.6 ± 3.9
		0.5	157	13	80 - 103	92.7 ± 7.7
Pepper (Greenhouse)	Fenhexamid	5.0	157	3	73 - 82	77.7 ± 4.5
		0.05	164	8	86 - 99	93.8 ± 5.0
Tomato (Greenhouse)	Fenhexamid	0.5	164	17	79 - 99	88.7 ± 5.5

TABLE C.2. Stability of Fenhexamid Residues in Various Matrices Following Storage at ca. –20 °C.

Commodity	Spike level (mg/kg)	Storage interval (days)	Recovered residues (mg/kg)	% recovery[1]
Kiwifruit	5.0	145	4.5 – 4.6	90-92
Peach	5.0	221 - 223	3.8 – 4.2	76-84
Cherry, sweet	5.0	214 - 216	3.8 – 4.1	76-82
Tomato	0.5	365	See Table C.1[2]	approx 79-99